

out of the current physician supervision requirement, and that the opt-out is consistent with State law.

(2) The request for exemption and recognition of State laws, and the withdrawal of the request may be submitted at any time, and are effective upon submission.

[51 FR 22042, June 17, 1986 as amended at 57 FR 33900, July 31, 1992; 66 FR 56769, Nov. 13, 2001; 71 FR 68694, Nov. 27, 2006]

§ 482.53 Condition of participation: Nuclear medicine services.

If the hospital provides nuclear medicine services, those services must meet the needs of the patients in accordance with acceptable standards of practice.

(a) *Standard: Organization and staffing.* The organization of the nuclear medicine service must be appropriate to the scope and complexity of the services offered.

(1) There must be a director who is a doctor of medicine or osteopathy qualified in nuclear medicine.

(2) The qualifications, training, functions, and responsibilities of nuclear medicine personnel must be specified by the service director and approved by the medical staff.

(b) *Standard: Delivery of service.* Radioactive materials must be prepared, labeled, used, transported, stored, and disposed of in accordance with acceptable standards of practice.

(1) In-house preparation of radiopharmaceuticals is by, or under, the direct supervision of an appropriately trained registered pharmacist or a doctor of medicine or osteopathy.

(2) There is proper storage and disposal of radioactive material.

(3) If laboratory tests are performed in the nuclear medicine service, the service must meet the applicable requirement for laboratory services specified in § 482.27.

(c) *Standard: Facilities.* Equipment and supplies must be appropriate for the types of nuclear medicine services offered and must be maintained for safe and efficient performance. The equipment must be—

(1) Maintained in safe operating condition; and

(2) Inspected, tested, and calibrated at least annually by qualified personnel.

(d) *Standard: Records.* The hospital must maintain signed and dated reports of nuclear medicine interpretations, consultations, and procedures.

(1) The hospital must maintain copies of nuclear medicine reports for at least 5 years.

(2) The practitioner approved by the medical staff to interpret diagnostic procedures must sign and date the interpretation of these tests.

(3) The hospital must maintain records of the receipt and disposition of radiopharmaceuticals.

(4) Nuclear medicine services must be ordered only by practitioner whose scope of Federal or State licensure and whose defined staff privileges allow such referrals.

[51 FR 22042, June 17, 1986, as amended at 57 FR 7136, Feb. 28, 1992]

§ 482.54 Condition of participation: Outpatient services.

If the hospital provides outpatient services, the services must meet the needs of the patients in accordance with acceptable standards of practice.

(a) *Standard: Organization.* Outpatient services must be appropriately organized and integrated with inpatient services.

(b) *Standard: Personnel.* The hospitals must—

(1) Assign an individual to be responsible for outpatient services; and

(2) Have appropriate professional and nonprofessional personnel available.

§ 482.55 Condition of participation: Emergency services.

The hospital must meet the emergency needs of patients in accordance with acceptable standards of practice.

(a) *Standard: Organization and direction.* If emergency services are provided at the hospital—

(1) The services must be organized under the direction of a qualified member of the medical staff;

(2) The services must be integrated with other departments of the hospital;

(3) The policies and procedures governing medical care provided in the emergency service or department are established by and are a continuing responsibility of the medical staff.

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(b) *Standard: Personnel.* (1) The emergency services must be supervised by a qualified member of the medical staff.

(2) There must be adequate medical and nursing personnel qualified in emergency care to meet the written emergency procedures and needs anticipated by the facility.

§ 482.56 Condition of participation: Rehabilitation services.

If the hospital provides rehabilitation, physical therapy, occupational therapy, audiology, or speech pathology services, the services must be organized and staffed to ensure the health and safety of patients.

(a) *Standard: Organization and staffing.* The organization of the service must be appropriate to the scope of the services offered.

(1) The director of the services must have the necessary knowledge, experience, and capabilities to properly supervise and administer the services.

(2) Physical therapy, occupational therapy, or speech therapy, or audiology services, if provided, must be provided by staff who meet the qualifications specified by the medical staff, consistent with State law.

(b) *Standard: Delivery of services.* Services must be furnished in accordance with a written plan of treatment. Services must be given in accordance with orders of practitioners who are authorized by the medical staff to order the services, and the orders must be incorporated in the patient's record.

§ 482.57 Condition of participation: Respiratory care services.

The hospital must meet the needs of the patients in accordance with acceptable standards of practice. The following requirements apply if the hospital provides respiratory care service.

(a) *Standard: Organization and Staffing.* The organization of the respiratory care services must be appropriate to the scope and complexity of the services offered.

(1) There must be a director of respiratory care services who is a doctor of medicine or osteopathy with the knowledge experience, and capabilities to supervise and administer the service properly. The director may serve on either a full-time or part-time basis.

(2) There must be adequate numbers of respiratory therapists, respiratory therapy technicians, and other personnel who meet the qualifications specified by the medical staff, consistent with State law.

(b) *Standard: Delivery of Services.* Services must be delivered in accordance with medical staff directives.

(1) Personnel qualified to perform specific procedures and the amount of supervision required for personnel to carry out specific procedures must be designated in writing.

(2) If blood gases or other laboratory tests are performed in the respiratory care unit, the unit must meet the applicable requirements for laboratory services specified in § 482.27.

(3) Services must be provided only on, and in accordance with, the orders of a doctor of medicine or osteopathy.

[51 FR 22042, June 17, 1986; 51 FR 27848, Aug. 4, 1986, as amended at 57 FR 7136, Feb. 28, 1992]

Subpart E—Requirements for Specialty Hospitals

SOURCE: 72 FR 15273, Mar. 30, 2007, unless otherwise noted.

§ 482.68 Special requirements for transplant centers.

A transplant center located within a hospital that has a Medicare provider agreement must meet the conditions of participation specified in §§ 482.72 through 482.104 in order to be granted approval from CMS to provide transplant services.

(a) Unless specified otherwise, the conditions of participation at §§ 482.72 through 482.104 apply to heart, heart-lung, intestine, kidney, liver, lung, and pancreas centers.

(b) In addition to meeting the conditions of participation specified in §§ 482.72 through 482.104, a transplant center must also meet the conditions of participation specified in §§ 482.1 through 482.57.

§ 482.70 Definitions.

As used in this subpart, the following definitions apply:

Adverse event means an untoward, undesirable, and usually unanticipated